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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,077	02/03/2006	Frank Theobald	5121002053	2323

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EXAMINER

WESTERBERG, NISSA M

ART UNIT	PAPER NUMBER
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1618

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05/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,077	Applicant(s) THEOBALD ET AL.	
	Examiner Nissa M. Westerberg	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 10 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 6, 8 - 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/3/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of a supporting layer where the supporting layer is composed of at least one organic polymer layer and the at least one ormocer layer is applied on both sides of the supporting layer in the reply filed on April 2, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The disclosure is objected to because of the following informalities: the use of the trademark "ormocer" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections - 35 USC § 112 2nd Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 – 6 and 8 – 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "readily" in claims 1 and 9 is a relative term which renders the claim indefinite. The term "readily volatile substance" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. How volatile a particular compound must be in order to be readily volatile is not defined in the specification and while nicotine is exemplified as a readily volatile substance, no definition or other examples of readily volatile substances are provided.

5. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 contains "characterized in that in each case" appears. It is unclear what the other cases involved in the invention are wherein this limitation must be met. It is also unclear which surfaces of the supporting layer must be coated as a layer has six surfaces – a "top", "bottom" and four sides.

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6. Claims 1 – 6 and 8 – 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims contain the trademark/trade name ORMOCER®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe inorganic-organic copolymers and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 2, 4 – 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwiatek et al. (4,710,191) in view of Amberg-Schwab et al. (J Sol-Gel Sci and Tech; Jan 2003, cited on PTO-1449).

Kwiatek et al. describes a therapeutic device for the transdermal administration of a medicament to the skin or mucosa of a host (abstract). Any drug which passes through the skin or mucosa can be employed in this device (col 7, ln 9 – 14). The device comprises a reservoir containing the active ingredient, a release layer formed on the

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inner surface of the inner surface of the reservoir (a peelable protective layer) and an active agent impermeable backing layer formed on the outer surface (col 2, ln 54 – 57). In figures 1 and 2, an active agent impermeable blocking layer (**106**), a heat sealable layer (**108**), and an outer backing layer (**110**) supporting an active agent impermeable pressure sensitive adhesive layer (**112**, fig. 2 only) are present on the outer surface of the drug reservoir. Suitable material for the backing layer **106** and outer backing layer **108** include the organic polymers cellophane, cellulose, plasticized vinyl acetate-vinyl chloride copolymers and polyethylene terephthalate, polyethylene or polypropylene (col 6, ln 38 – 45). The material in this layer can be a laminate of two or more films such as polyethylene/metallized polyethylene terephthalate/polyethylene laminate (col 6, ln 47 – 55). Determination of the suitable materials is dependent on the properties of the materials which are in contact with the barrier layer (col 6, ln 38 – 40).

Kwiatek et al. does not disclose the use of inorganic-organic copolymers as a suitable material for the outer backing layer.

Amberg-Schwab et al. discloses that inorganic-organic polymers can function as protection layers against unwanted migration of chemical substances by preventing components from migrating out of polymer substances and the coated materials are prevented against interactions with dyes or dirt that may stain the material (paragraph 1, abstract). These materials have excellent barrier properties for water vapor, oxygen and flavors (p 699, col 1, paragraph 1). In the determination of the barrier properties of these materials, a layer thickness of 4 μm was applied (p 700, col 2, paragraph 1). The properties of these material can be manipulated to prepare layers with different

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properties (see table 1, p 703). One type of these polymers (type-3), in addition to being a barrier to diffusion of gases and flavors, also provides for protection against staining, a longer lifetime of the coated polymers, and no electrostatic charging while providing a hydrophilic surface that the be refined using further processes such as printing (p 703, section 4). For example, identifying information could be printed on the inorganic-organic copolymer layer. Abrasion resistant surfaces can also be made using these materials (p 703, col 1, paragraph 3).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a transdermal therapeutic device as taught by Kwiatek et al. and to use the inorganic-organic polymer taught by Amberg-Schwab et al. as the impermeable polymer in the backing layer, given the barrier properties of these materials while imparting a number of other desirable features, such as abrasion resistance, increased polymers lifetimes due to plasticizing agent(s) not leaching from polymers and the ability to be printed with identifying information. Replacement of the barrier material polyethylene in the polyethylene/metallized polyethylene terephthalate/polyethylene laminate disclosed by Kwiatek et al. with the inorganic-organic copolymer results in a therapeutic device in which the covering film has a organic polymer polyethylene terephthalate layer coated on both the outer and inner faces with the inorganic-organic copolymer. In so doing, the materials in the polymer layers and the active ingredient in the reservoir would not escape and the exterior surface of the device would be resistant to abrasion, staining and could easily be printed.

In claim 2, the inorganic-organic copolymer is obtained by the hydrolytic condensation of organically modified silicon dioxides, which is not explicitly disclosed by the cited prior art. This is a product-by-process limitation. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) **MPEP 2113**.

11. Claims 1, 3, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwiatek et al. and Amberg-Schwab et al. as applied to claims 1, 2, 4 – 6 and 8 above, and further in view of Osborne et al. (US 5,004,610).

As discussed above, Kwiatek et al. and Amberg-Schwab et al disclose a transdermal therapeutic device in which a covering film having an organic polymer and the inorganic-organic copolymer with barrier properties covers a reservoir containing an active compound. The device also contains a peelable protective layer on the inner surface of the reservoir.

Neither reference discloses the use of nicotine as the active ingredient in the transdermal therapeutic device.

Osborne et al. discloses a transdermal delivery device comprising an impermeable backing material (**2** in figs 1 and 2), a nicotine reservoir (**3**), an adhesive

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membrane permeable to nicotine (5) with an optional strippable release liner that is removed prior to application to the skin (6; col3, ln 36 – 46). The backing layer is impermeable to nicotine and can be made of a variety of materials, including polyethylene terephthalate, polypropylene and polyvinylidene chloride (col 7, ln 37 – 46). The delivery of nicotine using the transdermal delivery system can be used to assist a smoker to stop smoking (col 1, ln 33 – 34).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a transdermal delivery device as taught by Kwiatek et al. and Amberg-Schwab et al., in which the backing layer comprises an organic polymer such as polyethylene terephthalate layer and a layer of an inorganic-organic copolymer and to use nicotine as the active ingredient, taught by Osbourne et al. as an active ingredient that is suitable for use in transdermal drug delivery systems which can be used to assist a smoker to stop smoking.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW